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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PORTNER, VIRGINIA ALLEN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,892	KWANG ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/12/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,14-18,35 and 36* is/are pending in the application.

4a) Of the above claim(s) *35 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 14-18* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☒ Claim(s) *1,2,4,14-18,35 and 36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 3,5-13 and 19-34 have been canceled by amendment.
Claims 1-2,4,14-18 and 35-36 are pending.
1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. ***Rejection Withdrawn***: Claim 18 rejected under 35 U.S.C. 102(b) as being anticipated by Muller et al (1991) is herein withdrawn in light of the amendment of the claim to remove the term "comprises".
2. ***Rejection Withdrawn*** Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Ogunniyi et al (1994) is herein withdrawn in light of the amendment of the claim to remove the term "comprises".
3. ***Rejection Withdrawn***: Claims 1-2, 7-13 rejected under 35 U.S.C. 102(b) as being anticipated by van Asten et al (1995) in light of the cancellation of claims 5-13 and amendment of claims 1-2 to no longer recite the term "flagellin protein".

Election/Restrictions

1. Newly submitted claims 35-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: All prior examined claims were directed to the utilization of either a fimbrial detection fragment or a flagella fragment, but NOT the combination of both. The new claims utilize a species of invention that is an independent and distinct combination reagent that was not previously examined. The combination of both fragments used in the claimed method is a method is a method that is independent and distinct from the methods that were previously examined that only utilized a single fragment, rather than the combination of two fragments as set forth in new claims 35-36.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 35 and 36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response To Arguments

1. ***Rejection Maintained***: The rejection of claims 1-2, 4, 14-17 under 35 U.S.C. 102(b) as being anticipated by Rajashekara et al (WO98/03656) is traversed on the grounds that SEQ ID NO 3 contains amino acids 38-165 and WO98' contains amino acids 2-165; the reference teaches only a larger antigenic fragment that does not anticipate nor render obvious the presently claimed invention.

2. It is the position of the examiner that the present claims recite open language "comprising" thus permitting the utilization of fragments of Salmonella enteritidis fimbrial protein SEF-14. Applicant's method claim 4 incorporates a fragment that is a fusion polypeptide (Instant claim 4) which is defined in the claims to be a polypeptide with additional amino acids fused to the fragment. Therefore, Rajashekara et al's fragment that is a fusion polypeptide and comprises a fragment of Salmonella enteritidis SEF14 fimbrial protein, (see page 11, lines 11-17 "additional amino acid residues added to the amino terminus" see SEQ ID NO 4) still anticipates the instantly claimed invention as now claimed.

3. ***Rejection Maintained***: The rejection of claims 1, 14-18 under 35 U.S.C. 102(b) as being anticipated by Thorns et al (US Pat. 5,510,241) in light of evidence provided by Rajashekara et al (WO98', provide evidence that a chicken food product that contains antibodies is eggs, and chicken product that includes antibodies is sera) is traversed on the grounds that the fimbrial antigen of Thorns et al is disclosed to immunoreact with S. Dublin as well as S.

enteritidis and the instantly claimed method utilizes a fimbrial antigen that "is active only against S. enteritidis" and there is no teaching or suggestion of this specific fragment in Thorns.

4. It is the position of the examiner that Thorns et al does disclose the utilization of fimbrial linear or continuous epitopes which are fragments/parts of the whole fimbrial SEF14 protein obtained from Salmonella enteritidis. The "epitopic parts (see abstract)" are disclosed for the specific purpose of detecting antibodies in a serum or egg yolk sample (see '241, col. 3, lines 9-15). Specific epitopic parts are described based upon monoclonal antibody binding (see all examples) and epitope binding regions being referred to an epitope cluster parts.

5. Thorns et al ('241) disclose fragments that comprise linear or continuous epitopes for the determination of diagnostic antibodies (detect chicken antibodies in a sample in an animal product or food sample (from a chicken), col. 17, lines 16-17), the antibodies being specific for S. enteritidis (see Thorns et al, '241, col. 28, claim 3, paragraph "(b)", monoclonal specific to S. enteritidis and not S. Dublin) , the fragments being defined by deposited monoclonal antibodies which do not include the entire fimbrial protein, at least one of the cluster parts, produced by enzymatic digestion resulting in oligopeptides or fragments of S. enteritidis SEF-14 protein (see col. 11, lines 12-25), would exclude the leader sequence region and therefore read at least one epitope fragments within the claimed range of amino acids of SEQ ID NO 3, as well as reads on variants of the claimed amino acid sequence based upon the disclosure within Thorns et al ('241) at col. 11, lines 26-35.

6. Applicant asserts that Thorns et al does not disclose SEQ ID NO 3.

7. It is the position of the examiner that the claimed invention includes fragments of SEQ ID NO 3 which are disclosed in Thorns et al. The claimed invention also includes amino acid sequences that are variants of SEQ ID NO 3, and variants of the fragments claimed based upon the recitation of the phrase "or a sequence wherein a conservative amino acid substitution is made for at least one amino acid in said sequence". Inherently Thorns et al anticipated the instantly claimed invention as now claimed because the reference provides disclosure for SEQ ID NO 2 of the instant Specification, which comprises SEQ ID NO 3, and Thorns et al discloses the utilization of epitope antigenic fragments to detect chicken antibodies in animal products and animal foods, and disclose deposited monoclonal antibodies to define the specific epitope containing fragment parts of instant SEQ ID NO 3, which are disclosed to be produced by enzyme digestion (see entire reference, Thorns et al) Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

New Claim Limitations/New Grounds of Rejection

Claim Objections

8. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

9. Claim 2 depends from claim 1 and defines the sample to be either "comprises sera or egg yolk" while claim 1 has been amended to define the biological sample to be "a biological sample comprising sera or egg yolk". Claim 2 is not further limiting of amended claim 1 which already recites the claim limitations of claim 2.

Claim Rejections - 35 USC § 112

10. Amended Claims 1-2, 4, 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. Claims 1-2, 4 and 14-17 have been amended to recite the phrase "or a sequence wherein a conservative amino acid substitution is made for at least one amino acid sequence in said sequence".

12. The newly added phrase is not defined by a specific reference SEQ ID NO based upon the introductory claim limitations "a sequence", which does not refer back to SEQ ID NO 3. The

claims as amended claim a method that utilizes a fimbrial protein from S. enteritidis, that evidences a least one conservative substitution but the starting sequence is not claimed, and where or how the sequence is changed is not defined by the claims. The sequence need only be a fimbrial protein, and is not limited to SEF-14. Therefore the claims have been amended to claim a new genus of sequences based upon the source of the antigenic fragment but not by a starting reference structure which must be changed, wherein the entire sequence may changed based upon the recitation of the phrase "at least one amino acid in said sequence" without the recitation of an upper limit on the number of changes.

13. The instant Specification only provides original descriptive support for specific SEQ ID Nos, fragments of the SEQ ID Nos, and substitutions within the recited SEQ ID Nos with the requirement that the conservative substitutions do not change the antigenic character of the resulting sequence from being able to immunoreact with an antibody in a biological sample. The claims are not limited to the embodiments disclosed and evidence original descriptive support in the instant Specification. The newly recited genus of sequences does not evidence original descriptive support in the instant Specification. All of the claims recite New Matter.

14. Claims 4, 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claims 4 and 14-17 recite claim limitations in the passive voice. The claims should recite active voice method steps and where an additional reagent is required by the claims, the phrase ---further comprises--- should be recited. The claims do not set forth the method/process, with

active, positive steps delimiting how this use is actually practiced. i.e. (claim 16).: -------further comprising the step of contacting said sample with----------.

16. Claim 15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the substrate for the enzyme so the detecting step can be carried out as required in claim 1. An enzyme that is only capable of a reaction would not function in the required methods step of "detecting" without the enzyme substrate that produces a detectable compound. A label that is only capable of producing a signal broadens the scope of the claim from which they depend as the independent claim requires the detection of the antibody/fimbrial fragment complex, and a label that does not detect due to the absence of the substrate would not serve in the positively recited detecting step of independent claim 1. See In re Mayhew.

17. Claim 18 recites the phrase "a sequence which corresponds to said sequence", but how does it correspond and what is the resultant fragment ? While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. The meets and bounds of the claim are unclear, because how the sequence has been changed and no longer is identical to SEQ ID NO 3, and therefore only corresponds there to, is not distinctly claimed. The term "sequence" on the last line of the claim can refer to the first recitation of "sequence" on line three or it can refer to the second recitation of the term "sequence" on line 4 or both; the claim is unclear.

Claim Rejections - 35 USC § 102

18. Amended Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Feutrier et al (1986).

Feutrier et al disclose an antigenic fragment of SEQ ID NO 3, specifically a 6-mer (hexapeptide, page 225, col. 1, paragraph 1 and also see Table 3, for fimbrin amino acid sequence for the 6-mer of S. enteritidis) from amino acid 39-44 (see page 225, col. 1, bottom of paragraph), wherein the fragment comprised an antigenic epitope recognized by anti-sera (see page 225, col. 1, paragraph 2, middle of paragraph) and shown to evidence hydrophilicity associated with antigenicity. Feutrier et al's fragment anticipates the instantly claimed invention as now claimed.

1. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

2. Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning

holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
June 5, 2006

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